

WEEK ENDING MAY 10, 2013

# **OPP Weekly Activity Report**

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#### FIELD & EXTERNAL AFFAIRS DIVISION

Antimicrobial Data Requirements Final Rule. This final rule published in the Federal Register of May 8. Once effective, this rule will revise the data requirements for antimicrobial pesticide products to reflect current scientific and regulatory practices and provide the regulated community with clearer and transparent information about the data needed to support pesticide registration decisions for antimicrobial products. The updated data requirements also serve to further enhance EPA's ability to make regulatory decisions about the human health and environmental fate and effects of antimicrobial pesticide products. These revisions are also expected to help protect human health and the environment by providing an up-to-date scientific framework for identifying and assessing the risks of antimicrobial pesticides sold or distributed in the United States. The rule becomes effective on July 8, 2013, 60 days after publication. (Kathryn Boyle, 305-6304)

CSPA Updated on PRIA III and Ingredients Disclosure. On May 7 and 8, Marty Monell, OPP Deputy Office Director, and Tracy Lantz, OPP Fellow in FEAD, presented at the Consumer Specialty Products Association mid-year meeting in Chicago. Marty spoke to the Federal Government Affairs Advisory Committee on PRIA III, Sequestration and Ingredients Disclosure. Tracy gave the Pest Management Products Committee further details of the current ingredients disclosure pilot, and this was followed by a discussion of increased participation and suggested improvements to the pilot. Over 500 individuals attended this conference. Additionally, Tracy met with Region 5 to discuss topics including ingredients disclosure, the proposed Bee Incident Guidance, pollinator protection statements on pesticide labels and DriftWatch™, a tool for enhancing communication between producers of specialty crops, pesticide applicators and managers of other sensitive areas including bee hives and fish farms. (Tracy Lantz, 308-6415).

Compliance Management PREP Course. The Pesticide Regulatory Education Program hosted the Compliance Management course in Davis, CA, from April 29 - May 2. There were 21 attendees from the FIFRA state lead agencies, plus one territory and one tribal representative. The course goal was to strengthen the skills of the managers and staff involved in compliance/enforcement programs in order to maximize operational efficiency and program success. Topics included next generation compliance and deterrence theories; management considerations in training, hiring and motivating staff; working effectively with tribal governments; inspector safety in an anti-government climate; issues surrounding pollinator protection; and working collaboratively with other state and federal agencies. Off-site presentations from the Office of Compliance,

Office of Civil Enforcement, Office of General Counsel and OPP/FEAD were very well received. (Dea Zimmerman, (312) 353-6344)

#### PESTICIDE RE-EVALUATION DIVISION

PCNB Bioaccumulation Assessment Incorporates FIFRA SAP- Recommended Approach. On May 6, 2013, EPA released an assessment of the potential for bioaccumulation and long-range transport of the organochlorine fungicide pentachloronitrobenzene (PCNB) and its degradates and contaminants. The assessment, titled, 2008 Science Advisory Panel Meeting Follow-Up: Assessment of the Bioaccumulation and Long-Range Transport Potential (LRTP) and [sic] of Pentachloronitrobenzene (PCNB) and Associated Ecological Risks (March 2010), incorporates many of the recommendations of the October 2008 FIFRA Scientific Advisory Panel (SAP) regarding approaches for evaluating pesticides characterized as persistent, bioaccumulative and toxic. The newly released assessment builds on and refines an earlier analysis of the bioaccumulative potential of PCNB, on which the agency's 2006 PCNB Reregistration Eligibility Decision was based. Many PCNB uses have been eliminated or restricted in recent years. The newly released assessment is important to the agency's consideration of the risks and benefits of the remaining pesticide products containing PCNB. EPA's 2010 assessment, 2006 PCNB RED and related documents are available in docket EPA-HQ-OPP-2004-0202 at www.regulations.gov. (Jill Bloom, 703-308-8019)

**OPP Holds Focus Meetings with Soap Salts End Use Registrants.** On May 8 and 9, 2013, members of the soap salts chemical team from EFED, RD, and PRD held two focus meetings with multiple end use registrants for the ammonium and potassium soaps of fatty acids (soap salts). The meetings were held to discuss and clarify soap salts product applications and to reduce uncertainties and conservative assumptions in the preliminary ecological risk assessment (PRA) for registration review. The PRA was finalized and posted for a 60-day public comment period on March 20, 2013, and included several "uncertain" endangered species risk conclusions. The registrants agreed to submit additional product information and typical use parameters to the docket which may help to refine the final ecological risk assessment. The soap salts final risk assessments and proposed registration review decision are expected later this year. Soap salts are registered for use as acaricides, algaecides, herbicides, insecticides and animal repellents (ammonium salts only) in various settings, chiefly residential and agricultural. More information is in the registration review docket, EPA-HQ-OPP-2008-0519. (Monica Wait, 703-347-8019)

#### ANTIMICROBIALS DIVISION

<u>Antimicrobial Registration Review DCIs Issued</u>. On April 25, 2013, the Antimicrobials Division issued the Glycolic acid and salts data call-ins (GDCI-000101-1065) to support the

upcoming registration review risk assessment. In the near future, a redacted (i.e., non-company specific) copy of the DCI mail-out package will be posted to the registration review docket (EPA-HQ-OPP-2011-0422) at <a href="https://www.regulations.gov">www.regulations.gov</a>. (Seiichi Murasaki, 703-347-0163)

Consumer Specialty Products Association (CSPA) Mid-Year Meeting. On May 8, 2013 Susan Lewis participated in the Antimicrobial Regulatory Meeting. The just issued EPA Rule for antimicrobial data requirements, 158W was a hot topic. Other items of interest included the ATP testing program, the sanitizer pilot, implementation of the OECD quantitative efficacy method, status of DCIs and the recent mister/fogger policy.

### BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

RV-PCR Method - Monthly Conference Call with OEM and ORD. As part of an ongoing partnership between the Office of Emergency Management (OEM) and the Office of Pesticide Programs (OPP) to develop EPA's anthrax analytical capability and preparedness in case of a wide-area anthrax event, the management and staff of the Microbiology Laboratory Branch participated in the monthly conference call with staff from OEM and the Office of Research and Development on May 6, 2013. The laboratory is conducting six practice sessions with the ORD developed RV-PCR method. Data from practice session 5 and a path forward were discussed. Practice session 5 demonstrated analyst proficiency with negative and positive samples while working as a team. To further challenge the analysts, the final practice session will be done independently by each analyst on a set of unknown samples. (Jafrul Hasan, 410-305-2657; Susan Lawrence, 410-305-2954)

Branch recently noticed that certain information included in the Product Performance Test Guidelines, OSCPP 810.2100 "Efficacy Data Recommendations for Sterilants" was incorrect. The document has been revised by citing the correct method and performance standard information, incorporating more detailed information on recommendations for testing with *Clostridium difficile*, shifting non-sterilant testing guidance to the "General Considerations" document, adding language to consult with Agency for products that have unusual claims not addressed in the guidance, and reformatting the document. The draft document was provided to the Antimicrobials Division for review. (Susan Lawrence, 410-305-2954)

#### INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

<u>Pollinator Protection Web Page Updated</u> – The ITRMD Web Team worked with FEAD and the OCSPP Communications Team to update the web page with the following documents: USDA and EPA Release New Report on Honey Bee Health,

Report on the National Stakeholders Conference on Honey Bee Health: Key Findings, and Report on the National Stakeholders Conference on Honey Bee Health. For more information, please visit <a href="http://www.epa.gov/opp00001/ecosystem/pollinator/index.html">http://www.epa.gov/opp00001/ecosystem/pollinator/index.html</a>. (Christine Tran, 703-305-1577)

<u>Pesticide News Stories Published</u> – The ITRMD Web Team worked with FEAD to publish the following Pesticide News Stories on the OPP website: <u>Comment Period Open on NMFS' Draft Measures to Protect Threatened and Endangered Pacific Salmon; EPA Releases Assessment of PCNB Bioaccumulation and Long Range Transport Potential; and <u>EPA Updates Data Requirements for Registration of Antimicrobial Pesticides</u>. (Christine Tran, 703-305-1577; Miriam Organic, 605-0583)</u>

<u>Presentations from EPA Workshop on New Provisions in PRIA 3 Available</u> – EPA held this workshop on April 10, 2013 and the slide presentations for both the plenary and break-out sessions are now available on the Pesticides website at <a href="http://www.epa.gov/pesticides/fees/pria3workshop/index.html">http://www.epa.gov/pesticides/fees/pria3workshop/index.html</a>. (Christine Tran, 703-305-1577)

<u>Pesticide Registration (PR) Notice 2013-1 Published</u> - The ITRMD Web Team worked with AD to publish PR Notice 2013-1 Silver Task Force North America (STFNA) on the Pesticides Website. This is an industry-wide association created to jointly develop data to support registration review under section 3(g) of FIFRA. For more information, please visit <a href="http://www.epa.gov/PR\_Notices/">http://www.epa.gov/PR\_Notices/</a>. (Carol Cotton, 703-305-5082)

<u>Update to the Microbiology Laboratory Antimicrobial Testing Methods and Procedures Site</u> - The ITRMD Web Team worked with BEAD to update several of the SOP Methods on the site. The SOPs are EQ-03-06: Calibration and

Maintenance of Weigh Balances, EQ-05-06: Calibration and Maintenance of Timers, and QA-04-05: Preparation and Maintenance of the Master Schedule. For more information please visit:

http://www.epa.gov/pesticides/methods/atmpa2z.htm. (Christine Tran, 305-1577)

OPP FOIA Request Status Report - April 29- May 3, 2013										
Requests Received		Requests Closed			Requests Open					
FY13	This Week	FY13	FYTD	This Week	FY13	Prior Years	Total			
285	9	145	236	9	132	133	265			

(Ana Espinoza, 703-347-0102)

#### BIOPESTICIDES & POLLUTION PREVENTION DIVISION

ILSI Conference Discusses Allergies, Sensitizing Properties of Proteins. On May 7 and 8, the International Life Sciences Institute (ILSI) Protein Allergenicity Technical Committee and the International Food Biotechnology Committee held a scientific conference for NAFTA regulators in Arlington, Virginia. The meeting was intended to update regulators on the two ILSI committee's activities on issues related to human health risk assessment for the products of agricultural biotechnology. Updates from Canada, Mexico and biotech-involved U.S. agencies were provided on streamlining review and approval of new products. Additionally, researchers funded by the EPA's STAR grant program in the Office of Research and Development presented on a variety of topics. The meeting was attended by about fifty international academic, regulatory and business representatives. (John Kough, 308-8267)

#### ESB Meets with Friends Community School Administrators on Tick IPM in Schools.

On May 9, representatives from BPPD's Environmental Stewardship Branch toured the campus and met with administrators from the Friends Community School in Greenbelt, MD. The school is a model for implementation of Tick Integrated Pest Management (IPM) in schools and is a Maryland Green Ribbon School for grades K-8. Discussion focused on the methods implemented to reduce exposure to ticks within their school, including personal protection, restrictions on play areas, and development of outreach materials. (Frank Ellis, 308-8107; Candy Brassard, 308-8107)

#### **FNVIRONMENTAL FATE & FFFFCTS DIVISION**

<u>Diclobenil Meeting with Registrant.</u> On May 9, OPP staff held a meeting via conference call with representatives from Chemtura, the diclobenil registrant. During the meeting, the group discussed data and lines of evidence that Chemtura may submit to request a waiver of two environmental fate studies for the Data Call In of diclobenil. OPP plans to issue the preliminary national ecological risk assessment for the registration review of diclobenil in early 2017. (Greg Orrick, 703-305-6140).

# **HEALTH EFFECTS DIVISION**

Meeting With Lee County Mosquito Control District: Staff from HED and RD participated in a meeting (5/6/13) with representatives from the Lee County Florida Mosquito Control District, including its executive director. The discussion focused on a series of label related issues but primarily it could be categorized as desire for more consistency amongst labels for mosquito control uses and developing a better understanding about the data used to evaluate mosquito control products and their associated uncertainties. Some specific issues which

were discussed included requirements for closed cockpit aircraft when the helicopters used don't have doors; glove requirements for some application scenarios including pilots; drift related language; aerial application parameters; and retreatment intervals. The possibility of these issues being raised in an AMCA (American Mosquito Control Association) context was also discussed. (Jeff Dawson, 305-7329)

Kresoxim-Methyl Conference Call: Meheret Negussie and Christine Olinger (HED/RAB3) and PRD had a conference call with BASF representatives to discuss condition of registration data of kresoxim-methyl that were discussed in the registration review preliminary work plan. BASF conveyed that they have developed a new LC/MS/MS method to determine residues in livestock matrices, which was validated by an independent laboratory. They will be submitting the studies to the Agency shortly. (Meheret Negussie 703-603-0086)

HED and RD Scientists Met with BASF Corporation: On May 9, 2013, BASF Corporation representatives met with the Health Effects Division (HED) to discuss the dosing levels for an animal feeding study to support the registration of Pendimethalin Technical. The Registration Division (RD), through Kable Davis, facilitated the meeting. The action is a PRIA R272 Study Protocol Review of the "Proposed Dosing for New Dairy Cow Feeding Study with Pendimethalin." BASF Corporation also proposed tolerance amendments for alfalfa and grass commodities in support of new use sites (i.e. rangelands and/or pasturelands). (Felicia Fort, Donald Wilbur and P. Yvonne Barnes 305-0091)

OPP-PMRA Quarterly Incident Workgroup Meeting OPP Staff from HED, EFED, ITRMD, and HED attended the joint incident meeting with Health Canada's Pest Management Regulatory Agency (PMRA). These meetings are held about four times per year between OPP and PMRA, and serve as periodic updates to both Agencies regarding current and upcoming activities and issues. During the meeting, a number of incident issues were discussed that are of mutual interest to both EPA/OPP and PMRA. Some highlights of the discussion include an EPA/OPP overview of our current Tier I incident case-review process and quantitative toxico-vigilance methods currently in exploratory development in HED that may be useful when evaluating incident data; sampling protocols; and reporting for bee incidents. (Elizabeth Evans, 703-305-7891)

#### **REGISTRATION DIVISION**

<u>New Uses Registered for Spirotetramat</u> On May 2, 2013, the Insecticide-Rodenticide Branch registered new uses for the insecticide, spirotetramat, on the following minor crops: taro leaves, watercress, pomegranate, banana, bulb vegetables crop group 3-07, globe artichoke, pineapple, coffee; and also added

crops to currently-registered uses on fruiting vegetables group 8-10, pome fruit group 11-10, citrus fruit group 10-10. Tolerances for spirotetramat on these crops were also established. The registrant, Bayer CropScience, requested amendment of its products, Spirotetramat Technical, Movento, and Ultor for the new registered uses. Spirotetramat is a systemic broad spectrum tetramic acid (keto-enol) insecticide. Its mode of action is lipid biosynthesis inhibition (LBI) that is active primarily by ingestion against immature insect life stages. Spirotetramat is registered for use on numerous crops, nursery and greenhouse. The Interregional Research Project No. 4 (IR-4) petitioned the tolerances for these uses as a pilot for the Regulatory Cooperation Council (RCC) joint review. RCC was created by order of President Obama and Prime Minister Harper to facilitate growth and trade between the United States and Canada. This pilot will help to re-evaluate current joint review practices and to better align domestic and import tolerance/maximum residue level (MRL) processes. In addition to the abovementioned crops, tolerances were established for bushberry, subgroup 13-07B and low growing berry, subgroup 13-07H, but these uses were not registered at this time due to requirements for residue data addressing possible pollinator exposure. (Rita Kumar, 703/308-8291)

Experimental Use Permit Granted to The Nature Conservancy for Control of Non-Native Argentine Ants in California Island Conservation Areas On May 6, 2013, the Insecticide-Rodenticide Branch granted an Experimental Use Permit to The Nature Conservancy to test the efficacy of thiamethoxam for controlling non-native Argentine ants (Linepithema humile) on California's Channel Islands. The Channel Islands are highly valued conservation areas, harboring a large number of endemic animal and plant taxa, and also supporting several plant communities that are now rare on the California mainland. Argentine ants are known to have harmful impacts on native ant populations and other arthropods. They also have direct and indirect negative effects on birds, mammals, and reptiles, as well as on plant-animal interactions and pollination and seed dispersal that ultimately affect plant regeneration and community composition. The presence of Argentine ants is therefore regarded as a major threat to biodiversity. Under the experimental program, two types of bait—a cooked egg/sugar mixture and sucrose in polyacrylamide casing—will be formulated using Optigard® Flex Insecticide (EPA Registration 100-1306). The bait will be deployed over 1600 acres of land—land owned by the National Park Service, the U.S. Navy, and The Nature Conservancy—on the California Channel Islands of Santa Cruz, San Clemente, and San Nicolas. The program is authorized through October 31, 2016, and is expected to contribute to efforts to protect native ants, other arthropods, and other native California species threatened by Argentine ants. (Julie Chao, 703/308-8735)

Chemical	Company	Registration	Action	ovement Act ( Due Date	Response		
		Number	Code*		Date		
The Fungicide Branch g							
Copper hydroxide	Quimetal Industrial S.A.	62562-10	R330	7/9/2013	5/7/2013		
		Domin	ic Schuler,	703/347-0260	)		
The Herbicide Branch g				1	T		
2,4-D, dimethylamine salt	NuFarm Americas, Inc.	228-715	R320	5/25/2013	5/8/2013		
	•	Betha	ny Benbow	, 703/347-807	2		
Paraquat dichloride	Liberty Crop Protection, LLC	89168-25	R301	5/7/2013	5/7/2013		
		Emily	Hartman,	703/347-0189			
Glycine, N- (phosphonomethyl)- Potassium salt Glyphosate Glyphosate-	Monsanto Company	524-537 524-421 524-475	R190	5/7/2013	5/6/2013		
isopropylammonium		324-473					
p.opj.a.miomam	Erik Kraft, 703/308-9358						
		59639-97	R170	5/9/2013			
Flumioxazin	Valent U.S.A. Corporation	59639-99 59639-119			5/9/2013		
Oryzalin	United Phosphorus, Inc.	70506-41	R340	5/13/2013	5/8/2013		
			t Rowland,	703/347-0254			
Atrazine	Swiss Farms Products	73327-3	R340	7/1/2013	5/8/2013		
			Maggie F	Rudick, 703/34	7- 0257		
The Insecticide Branch	<u> -                                     </u>						
Cypermethrin	S.C. Johnson & Son Inc.	4822-600	R310	7/1/2013	5/9/2013		
		BeWanda	Alexande	r, 703/305-746	0		
Imiprothrin	S.C. Johnson & Son Inc.	4822-447	R340	7/12/2013	5/62013		
Tolfenpyrad	Nichino America, Inc.	71711-30	R340	7/26/2013	5/6/2013		
	Melody Banks, 703/305-5413						
Piperonyl butoxide	Valent BioSciences Corporation	73049-495	R331	6/3/2013	5/3/2013		
	Carmen Rodia, 703/306-0327						
The Insecticide-Rodenti	cide Branch granted:						
Diflubenzuron	Chemtura Corporation	400-593	R320	5/22/2013	5/3/2013		
			Julie Chao				
Sulfuryl fluoride	Dow AgroSceinces LLC	62719-4	R340	5/9/2013	5/7/2013		
		Ri	ta Kumar,	703/308-8291			
Sulfoxaflor	Dow AgroSciences LLC	62719-623 62719-625	R10	5/17/2013	5/6/2013		

R10 – Food use(1); R170 – Additional food use; R190 – Additional food uses; 6 or more submitted in one application; R301 – New product identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner; R320 – New product; new physical form; requires data review in science divisions; R330 – New manufacturing-use product; registered active ingredient; selective data citation; R331 – New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only; and R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient)